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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/831,757      | 08/21/2001  | Jelle Wouter Slootstra | WE/P21526USOO       | 9985             |

466 7590 07/29/2003

YOUNG & THOMPSON  
745 SOUTH 23RD STREET 2ND FLOOR  
ARLINGTON, VA 22202

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| EXAMINER |
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WESSENDORF, TERESA D

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| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/831,757 | <b>Applicant(s)</b><br>SLOOTSTRA ET AL. |  |
|                              | <b>Examiner</b><br>T. D. Wessendorf  | <b>Art Unit</b><br>1639                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/2/03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> . | 6) <input type="checkbox"/> Other:  |

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**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-11, species: amino acid as the building block in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the restriction is not proper since the inventions are not independent and distinct. And the examination of all the pending claims does not place a serious burden on the examiner. It is further argued that the present national stage application was subject to examination during the international phase of the PCT application. The International examiner found no lack of unity, applying the same legal standards to the identical facts. The U.S. examiner has the considerable benefit of the search results generated by the international examiner, on the basis of all twelve pending claims.

Upon reconsideration of the restriction requirement and applicants' arguments, the restriction is withdrawn. All of the twelve claims will be examined on the merits.

***Status of Claims***

Claims 1-12 are pending and under examination.

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### **Specification**

The abstract of the disclosure is objected to because it uses phraseology often used in patent claims e.g., "comprising". Correction is required. See MPEP § 608.01(b).

### **Arrangement of the Specification**

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).

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- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities: Grammatical errors e.g., "may suitable" at page 5, line 21 and spelling errors such as "pharmaca" and "vaccins" at page 1, lines 4-5.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Information Disclosure Statement***

The listing of references in the specification (page 15, line 10 up to page 16, line 5) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the

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references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific mimotope sequences obtained from the method using, specific library and steps, does not reasonably provide enablement for the broad scope of the method using any random library containing any amino acid building block that results in any type of amino acid combinations i.e., mimotope sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The enabling disclosure provided in the specification is not commensurate with the broad scope of the claims. The claims cover numerous undefined variables. The disclosure provides a generalized statement as the generic claimed invention. It

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merely provides a list of the individual components that can be used in the general method. But the Examples, which has been provided as a guide to the invention, describes a method that comprises specific amino acid sequences that result in a specific mimotope sequences. There is nothing in the specification that teaches that the specific components provided in the Examples can be extrapolated to the claims as broadly written. And, in this highly unpredictable art, a priori statement, without any experimental studies, has not been deemed acceptable. It would require undue experimentation to determine from the list of individual components the ones that can be combined to cooperatively and effectively achieve the object of the instant invention. Furthermore, the specification fails to teach how to make a library in a minicard. (Ex parte Forman, 230 USPQ 546, BPAI, 1986).

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which applicant regards as the invention.

A. The claims are generally narrative, relative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document. For example: "is favored at said position", "random library of test sequences composed of building blocks"; "certain position"; "next library of test sequences"; "selected building blocks". Furthermore, the components of the methods do not have a characterizing or identifying feature that distinguishes one from the other. Claim 1 is being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method steps between step a) and b). There is no nexus among the process steps. "Providing" is not a positive, manipulative process steps. It is not clear as to what constitutes a providing step. It is not clear, within the claimed context, what constitutes a "flat support medium", especially in the absence of positive support in the specification.

B). Non sequitur for "the chemical composition of the test sequences" in claim 2. Furthermore, it is not clear within the context of the claim the "known" test sequences. In claims 2-11, it is suggested that the preamble "A" be changed to "The" as



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there is proper antecedent support for the method from the base claim.

C). Claim 3 recitation of an amount of receptor f) is inconsistent with the base claim. "Smaller" is a relative term especially as used in the claimed context.

D). Claims 4 and 5 are indefinite as to the recited "factor" and inconsistent with the base claim. It is not clear within the claimed context the metes and bounds of said factor.

E). Claim 6 is unclear as to how many step d) are contained in the claim. It is not clear which building block is replaced by a group of building block. The metes and bounds of the "at least one building block" and "group of building block" are not clearly circumscribed by the claim(s).

F). Claim 7 is unclear as to which test sequences is being referred to.

G). Regarding claim 9, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Also, this is an improper Markush grouping of the compounds and improper Markush language.

H). The use of the trademark BIACORE has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is suggested that the full name for the acronym AFM be spelled out.

I). Claim 11 is indefinite as to the physical separation of the test sequences and inconsistent with the base claim which does not recite said physical separation.

J). Claim 12 is indefinite with the use of the term "obtainable". It is not clear as to whether a mimotope has been positively obtained.

K). Claims 1-12 are rejected as indefinite for the reasons given by the examiner in the International application, Item VIII.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Pinilla et al (U.S. 5,556,762), Blake (U.S. 5,565,325), Blondelle et al (U.S. 5,645,996) or Hale (Immunotechnology) or Koster et al (Jrnl. of Immunological Methods) or applicants' disclosure of known prior art. [These references are applied as best as the claims can be understood].

Each of these references discloses specific methods of identifying a mimotope sequence utilizing specific components for the method. Each of these references therefore fully meets the broad claimed invention, which is subject to numerous interpretations. See the search report provided by the International examiner on 28 February 2000. As stated by applicants, this application has been examined by the international examiner, on the basis of all twelve pending claims. The claims were found anticipated by the international examiner based on the above variously cited references.

Applicants discloses at page 12, line 27 up to page 13, line 7 that "in previous studies it was shown that such a strategy, without obtaining an unfavorable signal to noise ratio, can result in hundreds of binding peptides that resemble small linear or non-linear parts of the native epitope.....in addition to random mini pepscan libraries mimotopes can also be

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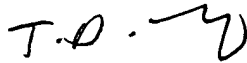
identified from standard pepscan libraries. These libraries contain all overlapping 12-mers....."

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
July 26, 2003